Exhibit B

Re: Re: WL cover letter用信息

From:	chengwei <chengwei@huahaipharm.com>
To:	李敏 <minli@huahaipharm.com>
Date:	Thu, 20 Dec 2018 15:46:28 +0000
Attachments:	CAPAs.docx (24.29 kB)

FYI

Wayne Cheng/程伟
Corporation Quality Management Dept
Zhejiang Huahai Pharmaceutical Co., Ltd
Xunqiao, Linhai, Zhejiang 317024, China
Email: chengwei@huahaipharm.com

发件人： 李敏
发送时间： 2018-12-20 22:20
收件人： chengwei
主题： Re: 转发: WL cover letter用信息

谢谢！ 有帮助。但最好能有一点对于我们Committed CAPAs update 的一些 high level summary.

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Min Li, PhD Vice President Huahai Pharmaceutical Co., Ltd

-----原始邮件-----
发件人:chengwei <chengwei@huahaipharm.com>
发送时间:2018-12-20 20:18:56 (星期四)
收件人: "李敏" <minli@huahaipharm.com>
抄送:
主题: 转发: WL cover letter用信息

敏总，
Linda说您这边需要一些用于写 WL cover letter的信息，不知道该以什么形式提供比较好，您看看按照下面这种模式有用吗？

We regret but recognized that the possibility of formation of NDMA based on the chemistry involved in the manufacturing Valsartan API was not foreseen due to the lack of the experience, and not fully understand the mechanistic chemistry at time in 2011, plus the failure to conduct thorough risk-based evaluation on possible impurity profiles is also a major factor from the first place, which together resulted in failure to identify the potential to generate NDMA in Valsartan API by process change (PCRC-11025). Even at the beginning of investigation in response to Novartis's complaint when NDMA was first identified by us, several factors which could contribute to presence of NDMA was not considered, hence the risk of potential nitrosamine impurity in other sartans was not fully identified. However, though the investigation of finding NDMA in valsartan API, we have gained tremendous knowledge and understand on the science and chemistry behind Sartan API product. In response to this NDMA event, the investigation conducted on NDMA as well as other mutagenic impurities in all APIs in Huahai is continuously updating. Generally the investigation has been separately conducted as four stages. Except on going stage 4 investigation, the first three stage investigations have been completed and documented, systematic risk assessments of all APIs in the Chuannan Site have been conducted and documented as part of extended investigation. Specifically, there are 5 Sartan products with potential risk of forming NDMA and NDEA as well as other impurities, for which ad-hoc risk assessment and investigation have been conducted and documented for each of them, risk control strategies have been proposed.

I2 failure to identify chloro analogue of 4-Bromomethyl-2-cyano-1,1'-biphenyl in time in *valsartan intermediates (C20213-17-339 and C20213-17-340)未汇总*

左乙拉希坦相关解释未汇总

In the responses specifically requested in this Warning Letter, the relevant corrective and preventive actions proposed and implemented by Huahai for better control NDMA content and other potential genotoxic impurities in our products are summarized. For details, please refer to each specific response hereunder ....

Wayne Cheng/程伟
Corporation Quality Management Dept
Zhejiang Huahai Pharmaceutical Co., Ltd
Xunqiao, Linhai, Zhejiang 317024, China
Email: chengwei@huahaipharm.com

发件人： chengwei
发送时间： 2018-12-20 20:11
收件人： Linda Lin

主题： WL cover letter用信息

Linda
按照下面这么写有用吗?
不说具体采取了什么整改，第一太多，第二列不全也麻烦的。标蓝部分的整改回复我还没看，部分是敏总负责回复的内容。

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缺1.2汇总 failure to identify chloro analogue of 4-Bromomethyl-2-cyano-1,1'-biphenyl in time in *valsartan intermediates (C20213-17-339 and C20213-17-340)*
缺左乙拉希坦相关解释汇总。

In the responses specifically requested in this Warning Letter, the relevant corrective and preventive actions proposed and implemented by Huahai for better control NDMA content and other potential genotoxic impurities in our products are summarized. For details, please refer to each specific response hereunder ....

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